Remarks

The applicant respectfully submits that claims 1-91 are patentable for the reasons provided below.

35 U.S.C. § 112, ¶ 2 (Completeness)

The applicant has been asked to show that claims 42-88 in this case are "complete," which is stated to be an issue of enablement. The applicant respectfully submits that the claims are proper in form and in substance.

One embodiment of the invention is shown for example in Figures 6, 8A and 8B, in which a cassette or subframe 154 can be removable from the afterloader. The cassette is described as follows in the specification:

> As shown in FIGS. 8A and 8B, the compact storage system of FIGS. 5-7 may readily be configured as a readily replaceable modular drive "cassette." In the cassette afterloader configuration of FIG. 8A and 8B, the storage and drive systems are contained on a readily detachable subframe 154 which can be removed from the afterloader housing containing the control system and other systems. The cassette includes the sourcewire drive and storage systems, radiation safe, and also includes the sourcewire position monitoring devices which are, preferably, adjusted and verified by the manufacturer before the cassette is shipped to the user. Because the sourcewire is already loaded into the drive and the function of the sourcewire monitoring devices verified before the cassette is delivered to the user, it can be installed by a relatively unskilled employee.

In some embodiments, the cassette 154:

- **includes** the force sensor 32 for detecting the force applied to advance the radioactive source in a catheter and for generating an output signal indicative of the force, see Figure 6, but
- **excludes** the circuit for controlling the advancement of the elongate lead in response to the output signal from the force sensor 32. That circuit can be part of the "afterloader housing

containing the **control system** and other systems," identified in the passage of the specification quoted above.

The specification thus shows that the cassette 154, which contains the perishable radioactive sourcewire, can be a separate article that is used as the vehicle for transporting the sourcewire. The present applicant is entitled to draft claims that are broad enough to cover the novel aspects of the cassette per se, just as the inventor of the audio cassette tape recorder would have been entitled to, and undoubtedly did, claim the cassette independent of the tape player with which it interacts. Therefore, at least some of the claims, for example independent claim 42, are broad enough to read on the cassette per se, and are no more incomplete than any claim to a subcombination.

Similarly, the claims do not need to recite the catheter as a positive element. Again, it is a separate part, commonly would be separately sold as a supply for each surgical procedure, and is not an essential element of the cassette, although the two interact during a surgical procedure.

Some of the claims, such as 88, do not recite a radioactive source, but this source is an independent part of the apparatus, likely to have a short useful life (since it decays over time), and might be manufactured by a different supplier from the cassette. Again, the applicant is entitled to claim a novel, separate commercial unit that happens to be used with other commercial units, as a subcombination, without claiming the complete assembly.

Finally, Section 2172.01 of the MPEP, cited in the Office action, only relates to "[a] claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record." The applicants do not believe that the specification discloses the circuit for controlling the advancement of the elongate lead in response to the output signal from the force sensor as "essential to the invention." Nor is the catheter or radioactive source disclosed as essential to the invention, although the invention does work with each of these.

Therefore, the claims are "complete."

Missing Claims

The applicant agrees with the Examiner that claims 92-112 as referred to in certain papers were never filed. The applicant elects to proceed with presently pending claims 1-91.

Obviousness Type Double Patenting

The judicially created rule against obviousness-type double patenting has been cited respecting claims 88-91 of this application and various claims of U.S. Patent No. 5,851,172 ("the original patent"). This double patenting rejection is respectfully traversed, as U.S. Patent No. 5,851,172 is the patent being reconsidered in this reissue proceeding. There can be no timewise extension of rights in this situation. The applicant will be required to surrender the original patent before it is replaced by the reissued patent. Only one of the two patents (the original patent and the reissued patent) will be in force at any time. Moreover, a reissued patent will expire on precisely the same day that the original patent was scheduled to expire. Since there will never be two patents in force at the same time, nor will there be any timewise extension of rights, there can be no double patenting.

35 U.S.C. § 132 (Amendments Supported)

The amendment to claim 42 positively reciting a radioactive source (that was non-positively recited before) is supported, for example, by the claim as originally filed and at col. 4, lines 3-5 which states as follows: "After the treatment plan is verified by the fluoroscopic images, the treatment is executed automatically by the afterloader using the radioactive-tipped sourcewire."

The amendment to claim 42 reciting "a force sensor for detecting the force applied to advance said radioactive source ... and for generating an output signal indicative of said force for controlling advancement of said radioactive source into the catheter" is supported in col. 5, lines 1-4 which state as follows: " A force sensor 32 adapted to resist movement of catheter adapter, such as a conventional strain gauge fixed to an end of a pivotally mounted retainer 302, measures the reactive force for input to the control system." This claim language is also supported at col. 8, lines 17-28, which state as follows: " As the sourcewire 62 advances, the control system

interrogates the force sensor 32 at intervals of approximately 0.3 millimeters. The control system compares the force readings to a predetermined force profile which has been preprogrammed into the control system based on, among other things, the type of catheter and the treatment being performed. The control system makes adjustments to the speed at which the sourcewire 62 advances at the same 0.3 millimeter intervals to keep the speed of advancement at the highest possible rate while maintaining the force level within the predetermined force profile."

The amendment to claim 43 "radioactive material" to "radioactive source" is supported on col. 1, lines 20-25 which states as follows: " the afterloader ... advances the radioactive source at the end of the wire, sometimes called a sourcewire, along the catheters according to a predetermined sequence calculated to deliver a therapeutic dose of radiation to the tumor."

The amendments in this paper are therefore free of new matter.

Conclusion

The applicant has shown that this application satisfies all the legal requirements pointed out by the Examiner. Therefore, the Examiner is respectfully requested to prepare a Notice of Allowability allowing all the pending claims (1-91).

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By: _____
George Wheeler
Reg. No. 28,766
Attorney for Applicant(s)

McANDREWS, HELD & MALLOY, LTD.
500 West Madison Street
Chicago, Illinois 60661
Telephone: (312) 775-8000

Docket No. 12844US01

Reissue claims after Amendment A for U.S. Patent No. 5,851,172

What is claimed is:

1. (Pending) An apparatus for advancing a radioactive source into and out of a catheter implanted in the body of a patient comprising:

- a housing adapted to receive an end of said catheter;
- an elongate lead adapted to support the radioactive source at an end thereof;
- means mounted to said housing for storing said elongate lead;
- a drive mechanism mounted to said housing for advancing said elongate lead into said catheter;
- a force sensor for detecting force required to advance said elongate lead into said catheter and for generating an output signal indicative of said force;
- an encoder for determining displacement of said elongate lead and for generating an output signal indicative of said displacement; and
- an electronic control system comprising circuit means responsive to the signals from said force sensor and from said encoder for controlling advancement of said elongate lead into and out of said catheter.

2. (Pending) The apparatus of claim 1 wherein said drive mechanism comprises a cylindrical disk having a single groove of one revolution disposed on an outer surface thereof, said disk being rotated about an axis thereof, said groove adapted for receiving said elongate lead from said storage means and advancing said elongate lead into said catheter, said elongate lead contacting said groove for at least about 10 degrees of arc.

3. (Pending) The apparatus of claim 2 further including:

- a guide tube for preventing buckling of said elongate lead, said guide tube having an open end fixed at a point proximal to a point where said elongate lead exits said groove tangent to said cylindrical disk as said elongate lead is advanced into said catheter.

4. (Pending) The apparatus of claim 3 further including:

- a second guide tube for preventing buckling of said elongate lead, said second guide tube having an open end fixed at a point proximal to a point where said elongate lead exits said groove tangent to said cylindrical disk as said elongate lead is retracted from said catheter and conveyed to said lead storage means.

5. (Pending) The apparatus of claim 2 further including means for urging said elongate lead against said groove.

6. (Pending) The apparatus of claim 5 wherein said urging means comprises an endless belt disposed between a plurality of capstans and said outer circumferential surface of said cylindrical disk.

7. (Pending) The apparatus of claim 1 further including:

- a plurality of capstans adjacent to said outer circumferential surface of said cylindrical disk for retaining said elongate lead in said groove.

8. (Pending) The apparatus of claim 1 wherein said storage means comprises an elongate tube mounted to said housing and having an opening proximal to said drive mechanism.

9. (Pending) The apparatus of claim 1 wherein said storage means comprises a substantially cylindrical drum having an outer cylindrical surface and being rotated about an axis thereof, said storage means further including means for displacing said drum along said axis responsive to rotation of said drum for urging said elongate lead to wind flat against said drum without overlapping.

10. (Pending) The apparatus of claim 9 further including means for urging said elongate lead against said outer cylindrical surface of said drum.

11. (Pending) The apparatus of claim 9 wherein said urging means comprises a plurality of capstans.

12. (Pending) The apparatus of claim 9 wherein said urging means comprises an endless belt disposed between a plurality of capstans and said outer circumferential surface of said drum.

13. (Pending) The apparatus of claim 1 wherein said drive mechanism and said storage means are housed in a separate unit that is readily detachable from said housing.

14. (Pending) The apparatus of claim 1 wherein said drive mechanism is pivotally attached to said housing and said force sensor comprises a load cell mounted along the axis of said elongate lead exiting said drive mechanism as it is advanced toward said catheter.

15. (Pending) The apparatus of claim 13 wherein said pivotal attachment is substantially along the axis of said elongate lead entering said drive mechanism as it is advanced out of said storage means.

16. (Pending) The apparatus of claim 1 wherein said catheter is slidably attached to said housing and said force sensor comprises a load cell adapted to sense a force tending to displace said catheter.

17. (Pending) The apparatus of claim 1 further including a direction changing capstan, said direction changing capstan slidably mounted to said housing and wherein said force sensor comprises a load cell adapted to sense a force tending to displace said direction changing capstan.

18. (Pending) The apparatus of claim 1 further including a catheter receiver for storing a plurality of catheters, at least one of said catheters having catheter information associated

therewith, a scanner for reading the catheter information, said electronic control system including further circuit means responsive to said catheter information for controlling advancement of said elongate lead into and out of said catheter.

19. (Pending) The apparatus of claim 18 wherein said catheter information is affixed to said at least one catheter.

20. (Pending) The apparatus of claim 18 wherein said scanner is incorporated into said catheter receiver.

21. (Pending) The apparatus of claim 1 further including a radiation safe for storing said radioactive source when not in use and further including an internal radiation sensor for verifying location of said radiation source within or without said radiation safe.

22. (Pending) The apparatus of claim 1 further including a shield external to said housing and an external radiation sensor for verifying the radioactive integrity of said shield.

23. (Pending) The apparatus of claim 19 wherein said catheter information comprises a bar code affixed to at least some of said catheters.

24. (Pending) The apparatus of claim 19 wherein said catheter information comprises a semiconductor chip embedded in at least some of said catheters.

25. (Pending) The apparatus of claim 19 wherein said catheter includes a balloon affixed to said catheter, said catheter information including any of the type of catheter, the catheter length, the catheter balloon length, the location of the catheter balloon along the length of the catheter and an inventory control number.

26. (Pending) The apparatus of claim 1 wherein said circuit means is responsive to said output signal of the force sensor to arrest advancement of said elongate lead when said output signal exceeds a predetermined value or rate of change.

27. (Pending) The apparatus of claim 1 wherein said circuit means includes means for interrogating the output signal generated by the force sensor at predetermined intervals of displacement of said elongated lead or at predetermined time intervals.

28. (Pending) The apparatus of claim 1 further including a catheter receiver for receiving said catheter, said catheter having catheter information associated therewith, a scanner for reading the catheter information, said electronic control system including further circuit means responsive to said catheter information for controlling advancement of said elongate lead into and out of said catheter.

29. (Pending) The apparatus of claim 28, wherein said scanner is incorporated into said catheter receiver.

30. (Pending) The apparatus of claim 1 wherein said force sensor includes means for monitoring a characteristic of said drive mechanism for advancing said elongate lead into said catheter.

31. (Pending) The apparatus of claim 30 wherein said drive mechanism includes a drive motor, said monitoring means comprising a current measuring circuit for monitoring the current supplied to said drive motor.

32. (Pending) An apparatus for advancing a radioactive source into and out of a catheter implanted in the body of a patient comprising a housing, an elongate lead adapted to support the radioactive source at an end thereof, a modular drive cassette replaceably mounted to said housing, said modular drive cassette having means for storing said elongate lead and drive means for advancing said elongate lead into said catheter and means for attaching and detaching said modular drive cassette to said housing for ready replacement of the cassette with another cassette having a new elongate lead with a radioactive source at the end thereof.

33. (Pending) The apparatus of claim 32 including a force sensor for detecting the force required to advance said elongate lead into said catheter and for generating an output signal proportional to said force, an encoder for determining displacement of said elongate lead and for generating a

signal indicative of said displacement and a control system comprising circuit means responsive to said signals for controlling advancement of said elongate lead into and out of said catheter in proportion to the output signal generated by said force sensor.

34. (Pending) The apparatus of claim 33 wherein said circuit means is responsive to said output signal of the force sensor to arrest advancement of said elongate lead when said output signal exceeds a predetermined value or rate of change.

35. (Pending) The apparatus of claim 33 wherein said circuit means includes means for interrogating the output signal generated by the force sensor at predetermined intervals of displacement of said elongated lead or at predetermined time intervals.

36. (Pending) An apparatus for advancing and retracting a radioactive source into and out of the body of a patient comprising:

- a frame;
- an elongate lead adapted to support the radioactive source at an end thereof;
- means mounted to said frame for storing said elongate lead;
- drive means mounted to said frame for advancing said elongate lead along a path of travel into the patient;
- a force sensor for detecting the force required to advance said elongate lead into the patient and for generating an output signal proportional to said force; and
- circuit means responsive to the output signal of said force sensor for controlling advancement of said elongate lead into the patient in proportion to the output signal generated by said force sensor.

37. (Pending) The apparatus of claim 36 including an encoder for determining displacement of said elongate lead along the path of travel.

38. (Pending) The apparatus of claim 36, including a housing for supporting said frame, said elongate lead being stored in a cassette, and means mounted to said housing for replaceably attaching said cassette to said housing.

39. (Pending) An apparatus for advancing a radioactive source along a tortuous path to a target site in the body of a patient comprising:

- a housing adapted to receive a proximal end of a catheter implanted in the patient along said tortuous path with a distal end of the catheter at or near the target site;
- an elongate lead having a proximal end and a distal end, said radioactive source being secured at the distal end of the lead;
- a radiation-proof safe coupled to said housing for storing at least the distal end of the lead when not advanced into the patient;
- drive means mounted to said housing and secured to the proximal end of the lead for selectively advancing the distal end of the lead from the safe and into the catheter via the housing, and for selectively retracting the distal end of the lead into the safe;
- a force sensor for detecting the magnitude of the force exerted by the drive means on the lead during advancement of the distal end thereof through the catheter and for generating an output signal indicative of said force; and
- feedback control means responsive to the magnitude of the exerted force detected by the force sensor for adjustment thereof to prevent buckling of the lead or puncture of the catheter when the distal end of the lead encounters obstructions or curves in the tortuous path during advancement thereof through the catheter.

40. (Pending) An apparatus for advancing a radioactive source into and out of a catheter implanted in a patient, comprising an elongate lead having said radioactive source secured at the distal end thereof, drive means for advancing and retracting the distal end of said lead into and from the catheter, a modular cassette replaceably mounted to said drive means and including means for storing at least the distal end of the lead in a radiation-proof safe, and means for attaching and detaching the modular cassette to the drive means for ready replacement of the cassette with another cassette having a new elongate lead with radioactive source at the distal end thereof.

41. (Pending) A method of advancing a radioactive source along a tortuous path to a target site in the body of a patient, comprising:

- implanting a catheter in the patient along said tortuous path with a distal end of the catheter at or near the target site;
- storing at least the distal end of an elongate lead having said radioactive source secured at the distal end thereof in a radiation-proof safe when not advanced into the patient;
- selectively advancing the distal end of the lead from the safe and into the catheter;
- detecting the magnitude of the force exerted on the lead during advancement of the distal end thereof through the catheter;
- responding to feedback of the magnitude of the detected exerted force to adjust the exerted force to prevent buckling of the lead or puncture of the catheter when the distal end of the lead encounters obstructions or curves in the tortuous path during advancement thereof through the catheter; and
- selectively retracting the distal end of the lead into the safe after completing a procedure therewith.

42. (Amended) An apparatus for advancing a radioactive source into a patient, the apparatus comprising:

(a) a radioactive source;

(b) a housing adapted to receive a catheter and adapted for storing said radioactive source;

(c) a drive for advancing said radioactive source from the housing into a catheter;

(d) a force sensor for detecting the force applied to advance said radioactive source in a catheter and for generating an output signal indicative of said force for controlling advancement of said radioactive source into the catheter.

43. (Amended) The apparatus of claim 42, further comprising an elongated carrier, wherein said radioactive source is secured on a portion of said elongated carrier.

44. (Pending) The apparatus of claim 43, wherein said elongated carrier is a column adapted to be pushed into a catheter.

45. (Pending) The apparatus of claim 44, further comprising a storage tube mounted to said housing and having an opening proximal to said drive.

46. (Pending) The apparatus of claim 43, wherein said drive engages and drives said elongated carrier to advance the radioactive source.

47. (Pending) The apparatus of claim 46 wherein said drive comprises a cylindrical disk having a single groove of one revolution disposed on an outer surface thereof, said disk being rotated about an axis thereof, said groove adapted for receiving said elongated carrier and advancing said radioactive source into a catheter, said elongated carrier contacting said groove for at least about 10 degrees of arc.

48. (Pending) The apparatus of claim 47 further including a guide tube for preventing buckling of said column.

49. (Pending) The apparatus of claim 48, said guide tube having an open end fixed at a point proximal to a point where said column exits said groove tangent to said cylindrical disk as said column is advanced into a catheter.

50. (Pending) The apparatus of claim 48, further including: a second guide tube for preventing buckling of said column.

51. (Pending) The apparatus of claim 47 further including a biasing element for urging said elongated carrier against said groove.

52. (Pending) The apparatus of claim 46, wherein said drive is secured to said housing by a pivotal attachment and said force sensor comprises a load cell mounted along the axis of said elongated carrier exiting said drive as it is advanced toward a catheter.

53. (Pending) The apparatus of claim 52 wherein said pivotal attachment is substantially along the axis of said elongated carrier entering said drive mechanism as it is advanced toward a catheter.

54. (Pending) The apparatus of claim 43, wherein said radioactive material is located on a distal portion of said elongated carrier.

55. (Pending) The apparatus of claim 43, wherein said force sensor engages and detects the force applied to said elongated carrier.

56. (Pending) The apparatus of claim 43, further comprising an encoder for determining displacement of said elongated carrier and for generating an output signal indicative of said displacement.

57. (Pending) The apparatus of claim 56, further comprising an electronic control system responsive to the signals from said force sensor and from said encoder for controlling advancement of said radioactive source into and out of a catheter.

58. (Pending) The apparatus of claim 57, wherein said control system is responsive to said output signal of the force sensor to arrest advancement of said radiation source when said output signal exceeds a predetermined value or rate of change.

59. (Pending) The apparatus of claim 57, wherein said control system includes an updating system for interrogating the output signal generated by the force sensor at predetermined intervals of displacement of the radiation source or at predetermined time intervals.

60. (Pending) The apparatus of claim 57, further including a catheter scanner for reading catheter information associated with a catheter, said electronic control system controlling advancement of said elongate lead into and out of said catheter responsive to said catheter information.

61. (Pending) The apparatus of claim 43, further comprising a substantially cylindrical storage drum positioned to receive turns of said elongated carrier, said drum having an outer cylindrical surface and being rotated about an axis.

62. (Pending) The apparatus of claim 61, further including a drum indexer for displacing said drum along said axis responsive to rotation of said drum for urging the turns of said elongated carrier to wind flat against said drum without overlapping.

63. (Pending) The apparatus of claim 62 further including a biasing element for urging said elongated carrier against said outer cylindrical surface of said drum.

64. (Pending) The apparatus of claim 63 wherein said biasing element comprises a plurality of capstans.

65. (Pending) The apparatus of claim 64 wherein said biasing element comprises an endless belt disposed between said plurality of capstans and the outer cylindrical surface of said drum.

66. The apparatus of claim 42, further comprising an encoder for determining displacement of said radioactive source and for generating an output signal indicative of said displacement.

67. (Pending) The apparatus of claim 42, wherein said housing has a storage area for storing said radioactive source.

68. (Pending) The apparatus of claim 67, wherein said radioactive source and said storage area are housed in a separate unit that is readily detachable from said housing.

69. (Pending) The apparatus of claim 68, wherein at least a portion of said drive is housed in said separate unit.

70. (Pending) The apparatus of claim 42, wherein a catheter is slidably attached to said housing and said force sensor comprises a load cell adapted to sense a force tending to displace the catheter.

71. (Pending) The apparatus of claim 42 further including a direction changing capstan, said direction changing capstan slidably mounted to said housing and wherein said force sensor

comprises a load cell adapted to sense a force tending to displace said direction changing capstan.

72. (Pending) The apparatus of claim 42 further including a catheter receiver for storing a plurality of catheters.

73. (Pending) The apparatus of claim 42, adapted for use with a catheter having associated coded catheter information, further comprising a scanner for reading catheter information.

74. (Pending) The apparatus of claim 73, further comprising an electronic control system receiving and responding to catheter information by controlling the advancement of said radioactive source into and out of the catheter having associated coded catheter information.

75. (Pending) The apparatus of claim 73, wherein said housing has a catheter receiver to receive a catheter and said scanner is incorporated into said catheter receiver.

76. (Pending) The apparatus of claim 73, wherein the scanner is a bar code reader for reading catheter information including a bar code.

77. (Pending) The apparatus of claim 73 wherein the scanner is a semiconductor chip reader for reading catheter information on a chip associated with a catheter.

78. (Pending) The apparatus of claim 73, wherein said catheter information includes at least one of the following items of information: the type of catheter, the catheter length, whether the catheter has a balloon, the catheter balloon length, the location of the catheter balloon along the length of the catheter, and an inventory control number.

79. (Pending) The apparatus of claim 42, said housing further including a radiation safe for storing said radioactive source when not in use.

80. (Pending) The apparatus of claim 79, further including a radiation sensor associated with said housing for verifying the location of said radiation source within or without said radiation safe.

81. (Pending) The apparatus of claim 42, further comprising a shield external to said housing and an external radiation sensor for verifying the radioactive integrity of said shield.

82. (Pending) The apparatus of claim 42, further comprising a catheter connected to said housing.

83. (Pending) The apparatus of claim 43, wherein said force sensor engages and detects the force applied to said elongated carrier.

84. (Pending) The apparatus of claim 51 wherein said biasing element comprises a plurality of capstans adjacent to said outer circumferential surface of said cylindrical disk for retaining said elongate lead in said groove.

85. (Pending) The apparatus of claim 84, wherein said biasing element further comprises an endless belt disposed between said plurality of capstans and said outer circumferential surface of said cylindrical disk.

86. (Pending) The apparatus of claim 50, said second guide tube having an open end fixed at a point proximal to a point where said column exits said groove tangent to said cylindrical disk as said column is retracted from a catheter and conveyed to said housing for storing said radioactive source.

87. (Pending) The apparatus of claim 42 wherein said force sensor includes a monitoring feature for monitoring a characteristic of said drive for advancing said radioactive source into a catheter.

88. (Pending) The apparatus of claim 87 wherein said drive includes an electric motor and said monitoring feature measures the current supplied to said drive motor.

89. (Pending) An apparatus for advancing a radioactive source into a catheter implanted in the body of a patient comprising

(a) a housing,

(b) a radioactive source,

(c) a modular cassette adapted for storing said radioactive source;

(d) a coupling for removably attaching said modular drive cassette to said housing for ready replacement of the cassette with another cassette having a different radioactive source; and

(e) a drive for advancing the radioactive source from said cassette into a catheter.

90. (Pending) The apparatus of claim 89, wherein said radioactive source is a source of beta radiation.

91. (Pending) A method of advancing a radioactive source to a target site in the body of a patient, comprising:

(a) providing a radioactive source;

(b) storing the radioactive source in a radiation-proof safe;

(c) implanting a catheter in the patient with a distal portion of the catheter at or near the target site;

(d) advancing the radioactive source from the safe into the catheter to said distal portion;

(e) detecting the magnitude of the force exerted on the radioactive source during advancement of the radioactive source in the catheter;

(f) responding to feedback of the magnitude of the detected exerted force to maintain the exerted force within a maximum force limit;

(g) maintaining the radioactive source at said distal portion to irradiate said target site; and

(h) retracting the radioactive source into the safe after said maintaining step.